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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,074	02/13/2002	Arthur M. Brown	22884/04066	8304

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,074	BROWN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/28/2002</u> . | 6) <input checked="" type="checkbox"/> Other: <u>SEQ Alignments</u> . |

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Applicant's election without traverse of Invention II, Claims 12-16 in the reply filed on August 10, 2004 is acknowledged.

Claims 1-11 and 17-20 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 12-16 are currently under examination.

Priority is April 17, 1998.

The disclosure is objected to because of the following informalities:

At page 3, KChAP is described as a 62.4 kD protein. In humans, this protein is set forth in Fig. 3 as SEQ ID NO: 4. In rats, this protein sequence is set forth in Fig. 2 as SEQ ID NO: 2.

At page 4, the K α /K β binding domain of KChAP of Fig. 2 (rat; SEQ ID NO: 2) is stated to be SEQ ID NO: 5, and extends from T309-L407. The K α /K β binding domain of KChAP of Fig. 3 (human; SEQ ID NO: 4) is stated to be SEQ ID NO: 7, and extends from T309-L407.

Perusal of the sequences shows that SEQ ID NO: 5 is not found in SEQ ID NO: 2 while SEQ ID NO: 7 is found in SEQ ID NO: 2. SEQ ID NO: 5 is found in SEQ ID NO: 4, but not SEQ ID NO: 7. Thus, it appears that the sequence identifiers for NO: 5 and NO: 7 do not correspond to the full-length sequences are set forth in the specification, and the text of the specification do not correspond to the sequence identifiers.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In Claims 12-16, the acronym "KChAP" is not written out and is therefore indefinite. Additionally, once this term is written out, "protein" will be repeated, causing the claim to read awkwardly, that is "potassium channel associated protein protein".

In Claims 13 and 14, there is a period after "Fig". Only a single period can be in a claim to delineate the end of the claim. Therefore, Applicants should either write out "figure" or eliminate reference to the figures because this reference can be considered redundant to the sequence identifiers.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"KChAP" is not described with either a structure or a function, both required for written description of the claimed subject matter. Additionally, variants having at least 85% or 95% identity to SEQ ID NOs: 2, 4, 5, 6, 7, or 10 and having function are not set forth. Therefore, these claims lack written description.

Applicants may wish to amend the claims to recite structure (Claim 12) and function (Claims 12-16).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 12, 13, 15, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Chung et al. (December 5, 1997; Science 278:1803-1805).

Chung et al. teaches a mouse PIAS3 that inhibits STAT3 signal transduction. The PIAS3 polypeptide shares:

90.3% identity to instant rat SEQ ID NO: 2,

89% identity to human SEQ ID NO: 4,

87.4 % identity to rat/human consensus sequence SEQ ID NO: 6,

91% identity to human K α /K β binding domain SEQ ID NO: 5,

95% identity to rat K α /K β binding domain SEQ ID NO: 7, and

92.5% identity to rat/human consensus K α /K β binding domain SEQ ID NO:10.

Other art of record:

Applicants and the prior art of Chung et al. appear to have found the same protein and, each by assay, have determined that this protein appears has different functions. For example, Applicants have provided examples of the activity of KChAP. Chung et al. has also provided working examples of Stat3 signal inhibition by PIAS3. Thus, with actual working examples it cannot be said that the protein does not have one or the other function.

Ueki et al. (1999; J Hum Genet 44: 193-196) teach the isolation of human gene encoding PIAS3. Ueki et al. did not assay the activity of the encoded protein, and used sequence homology to the PIAS3 of Chung et al. to assert that their gene encoded PIAS3.

Kaser et al. (USP 6,465,200; priority to April 1, 1999) teach a human transcription factor regulatory protein which, by homology, they also likened to PIAS (col. 1, para. 5). Kaser et al. did not assay the activity; Kaser et al. claim SEQ ID NO: 2.

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Both Ueki et al. and Kaser et al. human sequences appears to comprise an additional N-terminal signal sequence of 1-45 or 1-54 amino acids when compared to the instant full-length rat SEQ ID NO: 2 and human SEQ ID NO: 4. Otherwise, these sequences are identical to instant human sequences SEQ ID NO: 4 and NO: 5. The sequences of Ueki et al. and Kaser et al. share 96.7 and 95.2% identity with rat SEQ ID NO: 2 and NO: 7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER